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(54) Title: LARYNGEAL MASK DEVICE

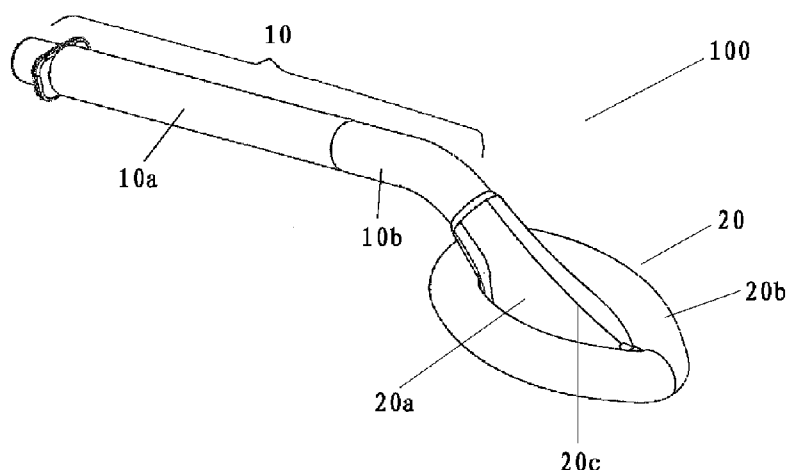


FIG. 1

(57) Abstract: Here provides a flexible airway tube structure (10) for a laryngeal mask device (100), which laryngeal mask device (100) includes a mask (20) with cuff structure (20b), wherein the flexible airway tube structure (10) can be connected to or formed integrally with the mask (20) and comprises a distal part (10b) and a proximal part (10a), and wherein the distal part (10b) is more rigid than the proximal part (10a). And, a method for preparing a flexible airway tube structure (10) for a laryngeal mask device (100) is provided, too. The flexible airway tube structure (10) has both good flexibility and good push-ability and can be manufactured easily.



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Laryngeal Mask Device

Technical field

The present disclosure generally relates to a laryngeal mask device (hereinafter referred to as a LM device), more specifically, but not limited to, a flexible airway tube structure and a cuff structure for a laryngeal mask device.

Technical Background

To perform general anesthesia for surgery, patient needs ventilatory support to maintain the patient hemodynamically stable anesthesia. Usually, there are two major airway devices during typically clinical procedure, that is, the endotracheal tube (ETT) ventilation device and a laryngeal mask device (LM device).

The ETT ventilation device comprises an elongate conduit constituted as tracheal tube, which is provided with an inflatable balloon at the distal end of the elongated tube. In operation, the distal end of the ETT is inserted into the patient's mouth, after the patient's throat inlet (or glottis opening), and into the patient's trachea. Once the conduit is positioned, the balloon and the internal passage of the trachea form a seal. After forming the seal, the ETT ventilation device is ventilated at the proximal end of the conduit to exert positive pressure to the patient's lungs. One of advantages of such ETT ventilation is that it can withstand greater sealing pressure, with less leakage. The main flaw is that it is difficult to properly insert the conduit, the technical requirements for the operator are too high.

A LM device is a medical device that keeps a patient's airway open during anaesthesia or unconsciousness. A LM device is most commonly used by anaesthetists to direct oxygen or anaesthesia gas to a patient's lungs during surgery and in the pre-hospital setting (for instance by paramedics and emergency medical technicians) for unconscious patients. A LM device generally includes a flexible airway tube structure defining an airway to direct oxygen or air from a source and a mask with an inflatable cuff structure, which is connected to the airway tube structure at its distal end and is able to be inserted through the patient's mouth, down the windpipe, and once deployed forms an airtight seal on top the glottis, so as to allow a secure airway to be managed by a health care provider.

The insertion of a LM device into the throat of a patient is an entirely straightforward procedure in most cases, which can be carried out successfully after readily understandable training. Therefore, in contrast with the ETT ventilation device, the insertion of LM device and the establishment of a breathing passage can be easier. In addition, even if the LM device is not properly inserted, the LM device can still establish a breathing passage. Thus, LM device is often thought of as a "life-saving" device.

However, circumstances do occasionally arise during insertion of the LM device, leading to undesirable positioning of the device and/or undesirable forces being applied to the device and/or to the patient.

One of the common circumstances is that the leading end of the device, i. e., the distal end of the fully deflated cuff structure becomes folded over on itself, presenting the more rigid distal end of the mask to catch the inside of the throat and subject the patient to undesirable forces.

During and/or after the insertion procedure, it is generally desirable to allow the airway tube structure having 360° access to the head and neck area of a patient. That is, it is desirable that an operator can place or secure the airway tube structure of the LM device in any direction to the head/or neck area of a patient. This requires that the airway tube structure has a degree of flexibility/softness. At the same time, it is not desirable that the sectional area of the airway defined by the airway tube structure is changed during the access to the head or neck area of a patient, that is, it is not desirable for the airway tube structure to kink.

In addition, it is desirable for the LM device to have good push-ability. That is, it is desirable to easily or conveniently push the mask with the cuff structure into the patient's mouth and to the top of the glottis, which requires that the LM device, especially the airway tube structure has a degree of rigidity/stiffness. In order to provide good push-ability and provide rigidity/stiffness to the airway tube structure, such a configuration, in which reinforcing spring 9 is added within the wall of airway tube structure, has been proposed, for example in a latest Chinese utility model CN204972582U.

However, in common sense, the flexibility and push-ability are not compatible. In other words, they are contradictory. If a LM device has good flexibility, it may have poor push-ability. If a LM device can be inserted easily, it may have poor flexibility. It is still difficult to get a balance between the flexibility and push-ability of the LM device.

In addition, it is still desirable to improve the leakage resistance of the LM device.

Summary of Disclosure

According to the present disclosure, there is provided a flexible airway tube structure for a laryngeal mask device having a mask with cuff structure, wherein the flexible airway tube structure comprises a distal part capable of being connected to or formed integrally with the mask and an opposite proximal part, and wherein the distal part being more rigid than the proximal part.

In some embodiments, the distal part comprises a thermally shrunk tube thereon.

In some embodiments, the wall of the distal part has a greater thickness than that of the proximal part.

In some embodiments, the flexible airway tube structure is a hollow tubular shape and the distal part has the same inner diameter as the proximal part and has a greater outer diameter than the proximal part.

In some embodiments, the distal part comprises a reinforcing structure that extends along an axial direction of the flexible airway tube structure.

In some embodiments, the reinforcing structure comprises axial wires.

In some embodiments, the distal part is made more rigid than the proximal part by chemical soaking of the distal part.

In some embodiments, the flexible airway tube structure comprises a PVC tube with plasticizer, and wherein the distal part of the PVC tube is soaked into ether for a predetermined period to dissolve the plasticizer to rigidify the distal part.

In some embodiments, the distal part of the PVC tube is soaked into ether for about 10 minutes at room temperature.

In some embodiments, the length of the distal part of the flexible airway tube structure is about 20% to 40% of the total length of the flexible airway tube structure.

In some embodiments, the length of the distal part of the flexible airway tube structure is about 5 mm.

In some embodiments, the flexible airway tube structure comprises a spiral spring structure to control the flexibility of the airway tube structure.

In some embodiments, the flexible airway tube structure comprises an intermediate part, which is located between the proximal part and the distal part and has a rigidity more than that of the proximal part and less than the distal part.

In some embodiments, in use, the distal part, together with the mask, is substantially inserted into the mouth of a patient, and the proximal part is substantially outside of the mouth of the patient

According to the present disclosure, it may provide a method for preparing a flexible airway tube structure for a laryngeal mask device having a mask with cuff structure, wherein the flexible airway tube structure comprises a distal part capable of being

connected to or formed integrally with the mask and an opposite proximal part, wherein the method comprising a step of making the distal part of the flexible airway tube structure more rigid than the proximal part thereof.

According to the present disclosure, there is provided a laryngeal mask device having a flexible airway tube structure as described above or prepared as above.

The laryngeal mask device according to the present disclosure has both good flexibility and good push-ability and can be easily inserted into the throat of a patient by an operator. Furthermore, the laryngeal mask device has 360° access to the head and neck area of a patient. In addition, the flexible airway tube structure and the laryngeal mask device can be manufactured easily.

According to the present disclosure, it may also provide a cuff structure for a laryngeal mask device, comprising: an inner-layer cuff that defines an annular main chamber of the cuff structure to be inflated or self-inflated; an outer-layer cuff that surrounds the inner-layer cuff; wherein the outer-layer cuff has a higher elongation rate and/or a thinner thickness than the inner-layer cuff so that the cuff structure can comply with the tissue structure of the patient very even.

In some embodiments, wherein a space is defined between the outer-layer cuff and the inner-layer cuff, and wherein the space is at substantially environmental pressure.

In some embodiments, wherein a space is defined between the outer-layer cuff and the inner-layer cuff, and wherein the space communicated with the annular main chamber.

In some embodiments, wherein the outer-layer cuff is connected to the inner-layer cuff at intervals.

In some embodiments, wherein the outer-layer cuff is substantially made of polyurethane and the inner-layer cuff is substantially made of PVC.

With this dual-layer cuff structure, the leakage resistance of laryngeal mask device will be improved.

Further features of the present invention will become apparent from the following description of exemplary embodiments with reference to the attached drawings.

Brief Description of the Drawings

- Fig. 1 schematically shows a perspective view of a LM device according to the present disclosure.

Fig. 2 schematically shows a top view of the LM device according to the present

disclosure.

Fig. 3 schematically shows a partial sectional view of the portion A in Fig. 2.

Fig. 4 schematically shows a partial sectional view of the portion B in Fig. 2.

Fig. 5 schematically shows a mask of the LM device from the bottom.

Fig. 6 schematically shows a portion of the inflatable cuff structure of the LM device according to the present disclosure in a perspective view.

Fig. 7 schematically shows the cross-section of the inflatable cuff structure of the LM device according to the present disclosure in an enlarged perspective view.

Detailed Description of the Embodiments

The embodiments will be described with reference to Figs. 1-7. However, the following embodiments are only examples for embodying the invention and are not intended to limit the scope thereof.

In the description of the embodiments, the term “proximal” is used with reference to a position closer to an operator or user of the LM device, and the term “distal” is used with a position farther from the operator or user of the LM device.

[First embodiment]

With reference to Figs. 1 and 2, The LM device 100 according to the present disclosure includes a flexible airway tube structure 10 and a mask 20 that is connected to or formed integrally with distal end of the airway tube structure. The airway tube structure 10 defines an airway 10c therein for supplying oxygen, air or anaesthesia gas and the like (see Fig. 3). The airway tube structure 10 is connected to a source of oxygen, air or anaesthesia gas and the like at its proximal end, such as a breathing machine.

With reference to Figs. 1 and 4, the mask 20 includes a supporting plate 20a and an inflatable cuff structure 20b. The supporting plate 20a functions to support the cuff structure 20b and is connected to the airway tube structure 10. In an exemplary embodiment, the inflatable cuff structure 20b is self-inflated and is generally kept in an inflated state. The cuff structure 20 has an elliptical or pear shape, which is close to the shape of inlet of the larynx, and can be inflated further or in a controlled manner after insertion through the inflating passage to establish a seal against the larynx, and can be deflated for easy removal from the larynx.

The inflating passage can be formed by a separate tube, which is generally positioned

outside of the cuff structure 20 and in communication with the chamber of the cuff structure. Alternatively, in the embodiment as shown, the inflating passage includes a first inflating passage portion 20c, which is connected with the inflating passage 10d of the airway tube structure 20, and a second inflating tube 20d, which communicates or reaches into the chamber of cuff structure 20. Preferably, the second inflating tube 20d reaches into the chamber of the cuff structure and is more rigid or stiffer than the cuff structure so that the front end of the cuff structure will be prevented from folding over itself during the insertion of the LM device.

Fig. 3 shows a partial sectional view of portion A of the airway tube structure 10. The airway tube structure 10 includes a tube wall that defines the interior of airway. Within the tube wall, the inflating passage 10d is provided to communicate with the first inflating passage 20c of the cuff structure so that the cuff structure 20 can be inflated further or in a controlled manner or be deflated by an outside inflating/deflating device (not shown).

Furthermore, preferably, a spiral spring structure 10e can be embedded in the wall of the airway tube structure 10 to reinforce the airway tube structure and also to keep the sectional area of the airway constant when it is bent or even kinked.

As described in the section of Technical Background, it is desirable for the LM device to have both good flexibility for 360° access to the head or neck area of a patient and good push-ability for easy insertion of the LM device.

Based on investigations and experiments, the inventors find that when inserting the LM device into the throat, the flexibility of the part of the airway tube structure 10, which is relatively close to the cuff structure 20, affects the push-ability more. That is, if this part is flexible, the LM device will have a poor push-ability due to for example the bending of this part. And, if this part is relatively rigid/stiffness, the LM device may have good push-ability. On the other hand, when an operator places or secures the airway tube structure to the head or neck area of a patient, the LM device would have good access to the head or neck area, if the part, which is close to the operator, in particular the part, which is outside of the mouth of the patient, is sufficiently flexible.

In the following, the description will be made with respect to the airway tube structure.

The airway tube structure 10 according to the present disclosure includes a proximal part 10a and a distal part 10b. The proximal part 10a is flexible for ease of the bending of the airway tube structure, and the distal part 10b is less flexible or more rigid or stiffer than the proximal part 10a for ease of the insertion of the LM device. Generally, the length of the distal part 10b is no more than 50% of the total length of the airway tube structure and is preferably 20%-40% of the total length of the airway tube structure. As an example, the total length of the airway tube structure is about 20

cm, and the distal part 10b is about 5 cm in length.

Optionally, the airway tube structure may have an intermediate part (un-shown in Figures), which is between the proximal part 10a and the distal part 10b and has a rigidity/stiffness between that of the proximal part and that of the distal part. That is, the intermediate part is more rigid than the proximal part and less rigid than the distal part.

In order to achieve this type of airway tube structure having sections or parts with different rigidity/stiffness, the distal part 10b of the airway tube structure has an additional thermally shrunk tube 10f onto it (as shown in Fig. 4). For example, adopting PET, PA, PTFE or FEP, etc. as the material for thermal shrinkable tube can improve the rigidity or stiffness of the distal part of the airway tube structure.

Alternatively, in order to achieve this type of airway tube structure having sections or parts with different rigidity/stiffness, the wall of the distal part 10b of the airway tube structure may have a greater thickness than the wall of the proximal part 10a. For example, the distal part 10b has the same inner diameter as the proximal part but has a greater outer diameter than the proximal part.

Alternatively, in order to achieve this type of airway tube structure having sections or parts with different rigidity/stiffness, the distal part 10b of the airway tube structure may additionally have longitudinal (axial) reinforcing structure, such as longitudinal wires.

The scope of the disclosure is not limited to the structures as described above for achieving this type of airway tube structure having sections or parts with different rigidity/stiffness. A person skilled in the art can anticipate other structures, which are also within the scope of the present disclosure.

Among the structures as described above for achieving this type of airway tube structure having sections or parts with different rigidity/stiffness, thermal shrinkable tube may be a preferable implementation.

Specifically, it is only necessary to slide or over-mold a thermal shrinkable tube onto the distal part of the airway tube structure and then subject the thermal shrinkable tube to heat, so that the thermal shrinkable tube will shrink and bond to the airway tube structure. According to the implementation, it is easy to make the manufacturing.

According to the first embodiment, the present disclosure has disclosed some implementations to achieve this type of airway tube structure having sections or parts with different rigidity/stiffness. According to the first embodiment, an additional structural feature, such as a step between the distal part of the airway tube structure, having a thermal shrinkable tube or greater thickness, and the proximal part of the

airway tube structure, or longitudinal reinforcing structure will be added to the airway tube structure.

[Second embodiment]

In the following, another embodiment to achieve this type of airway tube structure having sections or parts with different rigidity/stiffness, chemical soaking, will be described.

As an example, the flexible airway tube structure is made of a PVC tube comprised of PVC polymer and plasticizer. The plasticizer could be DEHP, DBP, and TOTM and so on. The flexibility or softness of the tube is related to the ratio of plasticizer concentration. More plasticizer, more flexibility/softness. It is interesting to find that generally this plasticizer could be dissolved into for example ether. Accordingly, when this kind of PVC tube was soaked into ether, plasticizer will be gradually dissolved. The PVC tube will become more and more hard or rigid by leaching out of the plasticizer.

The flexible airway tube structure may comprise a PVC (HY-VIN XH 79214 CLP42) tube with an outer diameter of about 11-12 mm, hardness of Shore A of about 68 ± 3 and with about 35%wt of plasticizer. The tube was soaked into around 100% analysis grade ether at room temperature for around 10 minutes, and then the hardness was distinctly improved.

The advantages of this leaching out or chemical soaking method are that the softness or stiffness can be adjusted easily by controlling different soaking time and soaking temperature and that the dimension or structure of the tube does not change, so that there is no additional structural feature.

It should be understood that the solution adopted in the chemical soaking or leaching out method is not limited to ether. There are other solutions to dissolving out the plasticizer. And, the solution could be chosen in accordance with the material of the tube as well as the component of the material, which makes the tube soft, as long as the solution can reduce the ratio of this component.

[Third embodiment]

In the following, another embodiment will be described with reference to Figs. 6 and 7. Fig. 6 schematically shows a portion of the inflatable cuff structure of the LM device according to the present disclosure in a perspective view. Fig. 7 schematically shows the cross-section of the inflatable cuff structure of the LM device according to the present disclosure in an enlarged perspective view.

The inflatable cuff structure 20b is a dual-layer cuff and includes: an inner-layer cuff

20b1 that is connected to or integral with the supporting plate 20a and defines an annular main chamber or inner space of the cuff structure to be inflated or self-inflated, wherein the annular main chamber or inner space defined by the inner-layer cuff 20b1 communicates with inflating passage; and an outer-layer cuff 20b2 that surrounds the inner-layer cuff 20b1. A small space can be defined between the inner-layer cuff 20b1 and the outer-layer layer cuff 20b2. The small space may be at environment pressure or communicate with the main chamber or inner space defined by the inner-layer cuff 20b1 so that the small space will be at the same pressure with the main chamber or inner space defined by the inner layer cuff 20b1.

Furthermore, the out-layer cuff 20b2 can also be connected or bonded to the inner-layer cuff 20b1 at intervals to form a pleated-shape.

The inner-layer cuff 20b1 is substantially made of for example PVC material, similar to the PVC material for the conventional single-layer cuff structure. However, for maintaining the annular main chamber or inner space, the selected PVC material, the inner-layer's thickness and its elongation cannot provide excellent compliance performance with the epiglottis tissue structure. According to the present embodiment, an outer-layer cuff 20b2, which is substantially made of a material that has a higher elongation rate and/or a thinner thickness than the material of the inner-layer cuff. For example, the inner-layer cuff 20b2 can be substantially made of polyurethane, which is one kind of elastomer polymer material with extreme high elongation rate, even with 200%-300% of elongation rate. So, the outer-layer cuff can comply with the tissue structure of the patient very even, with the leakage resistance improved.

A person skilled in the art can understand that the PVC material for the inner-layer cuff and the polyurethane material for the outer-layer cuff are just examples of the materials of the cuffs, and other suitable materials can also be adopted, as long as the inner-layer cuff can be inflated and can withstand the inflated pressure and the outer-layer cuff has a higher elongation and/or a thinner thickness to comply with the tissue structure of the patient much better.

An experiment is made to verify the leakage resistance of the LM device with this dual-layer cuff structure. In the experiment, a LM device with a single-layer cuff structure and a LM device with this dual-layer cuff structure are respectively inserted into an artificial throat and the leakage between the cuff structure and the artificial throat is measured. The result shows that the LM device with a single-layer cuff structure has a leakage of 40%, which is the ration of the amount of the leaked oxygen or air to the total amount of the pumped oxygen or air, whereas the LM device with a dual-layer cuff structure has a leakage of 6%. That is, the leakage is improved from 40% to 6% by this dual-layer cuff structure.

It should also be understood that the present disclosure is not limited to leaching out or chemical soaking method. Other methods, which can change the softness/hardness

of a tube to realize a tube having different stiff/rigid parts/segments, can be adopted.

CLAIMS

What claimed is:

1. A flexible airway tube structure for a laryngeal mask device having a mask with cuff structure, wherein the flexible airway tube structure comprises a distal part capable of being connected to or formed integrally with the mask and an opposite proximal part, and wherein the distal part being more rigid than the proximal part.
2. The flexible airway tube structure as recited in claim 1, wherein the distal part comprises a thermally shrunk tube thereon.
3. The flexible airway tube structure as recited in claim 1, wherein the wall of the distal part has a greater thickness than that of the proximal part.
4. The flexible airway tube structure as recited in claim 3, wherein the flexible airway tube structure has a hollow tubular shape, and wherein the distal part has the same inner diameter as the proximal part and a greater outer diameter than the proximal part.
5. The flexible airway tube structure as recited in claim 1, wherein the distal part comprises a reinforcing structure that extends along an axial direction of the flexible airway tube structure.
6. The flexible airway tube structure as recited in claim 5, wherein the reinforcing structure comprises axial wires.
7. The flexible airway tube structure as recited in claim 1, wherein the distal part is made more rigid than the proximal part by chemical soaking of the distal part.
8. The flexible airway tube structure as recited in claim 7, wherein the flexible airway tube structure comprises a PVC tube with plasticizer, and wherein the distal part of the PVC tube is soaked into ether for a predetermined period to dissolve the plasticizer so as to rigidify the distal part.
9. The flexible airway tube structure as recited in claim 8, wherein the distal part of the PVC tube is soaked into ether for about 10 minutes at room temperature.
10. The flexible airway tube structure as recited in claim 1, wherein the length of the distal part of the flexible airway tube structure is about 20% to 40% of the total length of the flexible airway tube structure.
11. The flexible airway tube structure as recited in claim 1, wherein the length of the distal part of the flexible airway tube structure is about 5 mm.

12. The flexible airway tube structure as recited in claim 1, wherein the flexible airway tube structure has a spiral spring structure to control the flexibility of the airway tube structure.
13. The flexible airway tube structure as recited in claim 1, wherein the flexible airway tube structure comprises an intermediate part, which is located between the proximal part and the distal part and has a rigidity more than that of the proximal part and less than the distal part.
14. The flexible airway tube structure as recited in claim 1, wherein, in use, the distal part, together with the mask, being able to be substantially inserted into the mouth of a patient, and the proximal part being able to be positioned substantially outside of the mouth of the patient.
15. A method for preparing a flexible airway tube structure for a laryngeal mask device having a mask with cuff structure, wherein the flexible airway tube structure comprises a distal part capable of being connected to or formed integrally with the mask and an opposite proximal part, wherein the method comprising a step of making the distal part of the flexible airway tube structure more rigid than the proximal part thereof.
16. The method as recited in claim 14, wherein the distal part of the flexible airway tube structure is made more rigid by providing a thermal shrinkable tube onto the distal part and then heating the thermal shrinkable tube to shrink it onto the distal part.
17. The method as recited in claim 14, wherein the distal part of the flexible airway tube structure is made more rigid by chemical soaking of the distal part.
18. The method as recited in claim 17, wherein the flexible airway tube structure is comprises a PVC tube with plasticizer, and the distal part is soaked into ether for a predetermined period to dissolve the plasticizer.
19. The method as recited in claim 18, wherein the distal part is soaked into ether for about 10 minutes at room temperature.
20. A laryngeal mask device comprising a flexible airway tube structure that is recited in any of claims 1 to 14 or prepared according to the method recited in any of the claims 15 to 19.

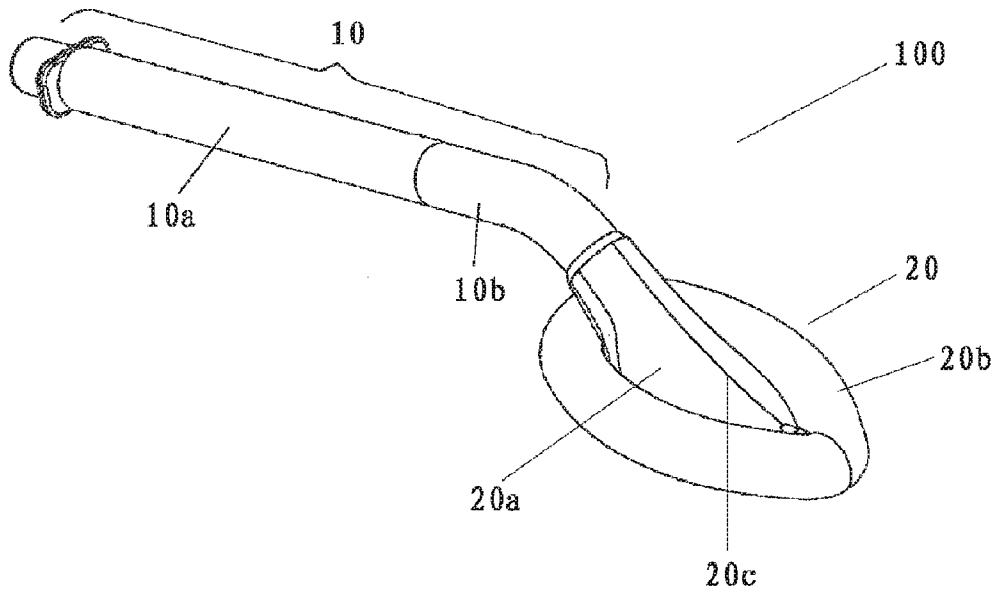


FIG. 1

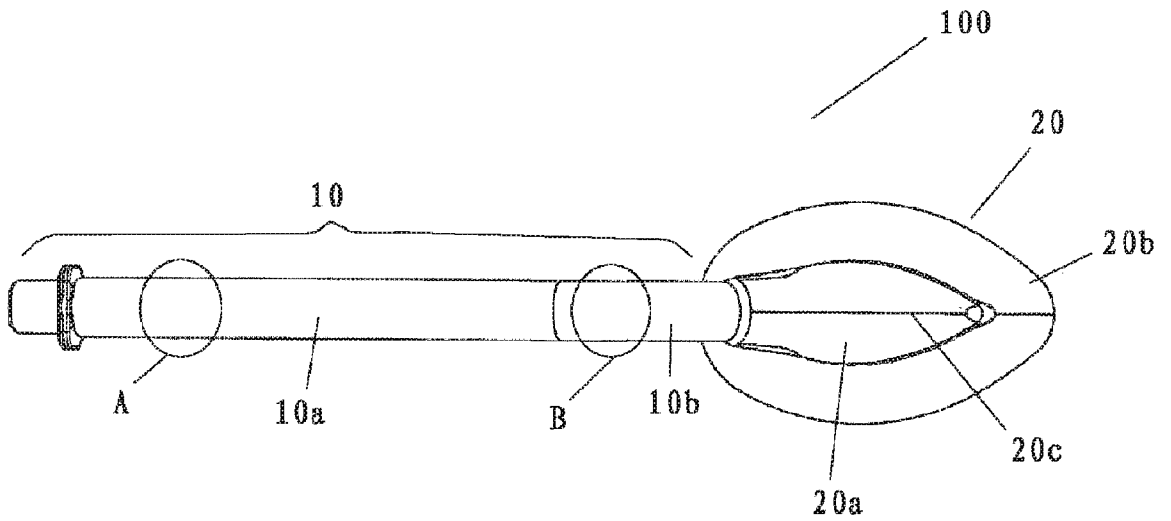


FIG. 2

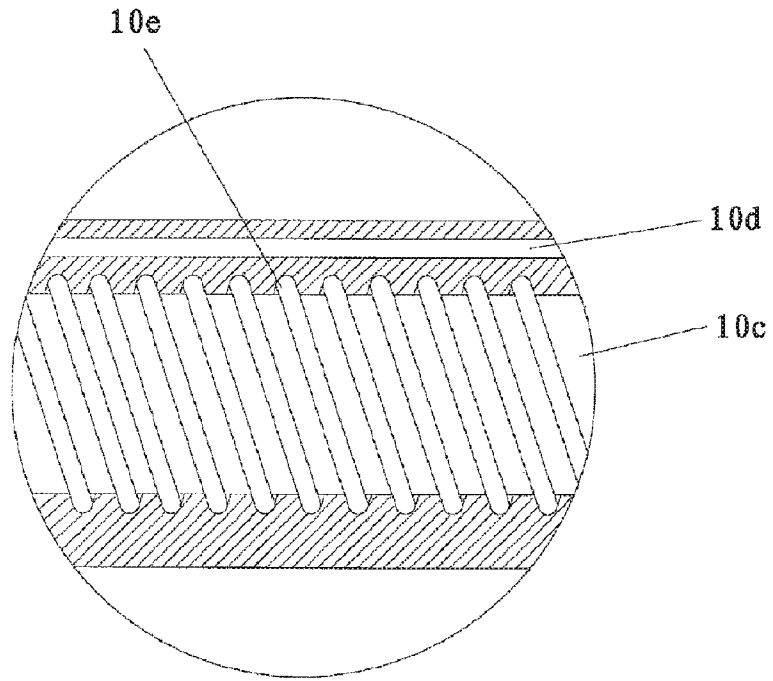


FIG. 3

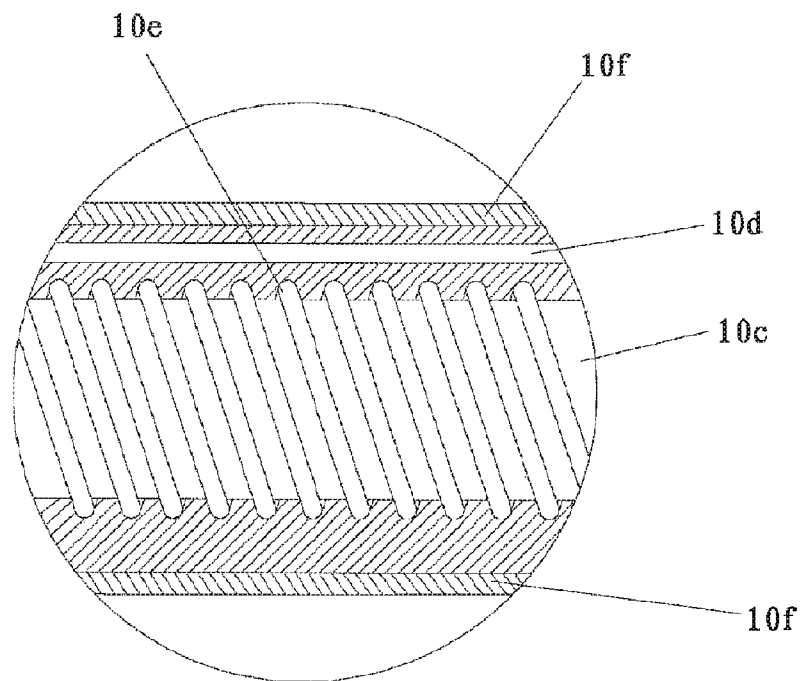


FIG. 4

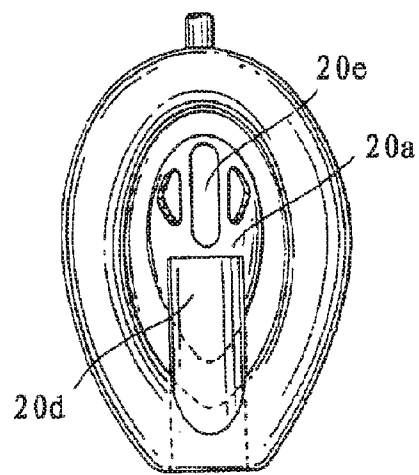
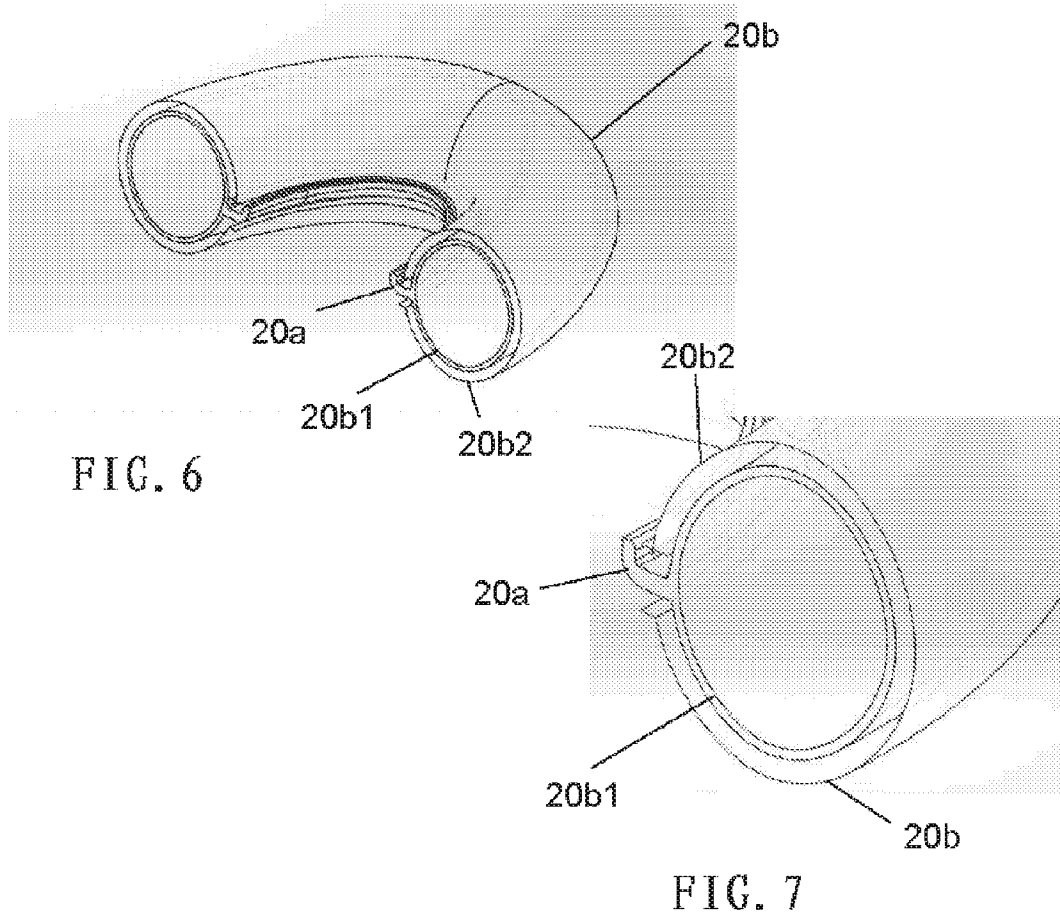


FIG. 5



INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2016/082971

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/04(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M16/+; A61M25/+

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CNPAT, CNKI, EPODOC, WPI: laryngeal, mask, larynx, cover, cuff, tube, rigid, stiff, airway, shrink, spring, rib.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 1771067 A (AMBU A/S) 10 May 2006 (2006-05-10) description, page 1, line 21-page 12, line 13 and figures 1A-12D	1, 3-11, 14-15, 17-20
Y	CN 1771067 A (AMBU A/S) 10 May 2006 (2006-05-10) description, page 1, line 21-page 12, line 13 and figures 1A-12D	2, 12, 16
Y	US 2016073855 A1 (VIVID MEDICAL, INC.) 17 March 2016 (2016-03-17) description, paragraphs [0002] and [0054]	2, 16
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A	CN 103180003 A (BASKA, KANAG ET AL.) 26 June 2013 (2013-06-26) the whole document	1-20
A	US 7546838 B2 (LIN, BIH-CHERN) 16 June 2009 (2009-06-16) the whole document	1-20

 Further documents are listed in the continuation of Box C. See patent family annex.

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